510(k) SUMMARY

MAY - 4 2007

NEXT GENERATION™ Anterior Cervical Plating System
510(k) SUMMARY
March 2007

Company: Alphatec Spine, Inc.
2051 Palomar Airport Road#100
Carlsbad, CA 92011 USA
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Contact Person: Paula Morgan, Director of Regulatory Affairs

Trade/Proprietary Name: *NEXT GENERATION*™ Anterior Cervical Plating System

Common Name: Anterior Cervical plate System

Classification Name: Spinal Intervertebral body fixation Orthosis (888.3060)

Product Description:
The NEXT GENERATION™ Anterior Cervical Plating System is an anterior cervical plating system intended for use in anterior cervical decompression and fusion (ACDF) surgery (C2-C7). The subject components of this submission are cervical plates, screws, and various instrumentation.

Indications for Use:
It is intended that this device, in any system configuration, be removed after the development of solid fusion mass of spinal segments in skeletally mature patients.

The NEXT GENERATION™ Anterior Cervical Plate system is intended for use in anterior cervical decompression and fusion (ACDF) surgery (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of fusion in patients with the following conditions:

- degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- tumor
- pseudoarthrosis
- and failed previous fusion.

Substantial Equivalence:

The NEXT GENERATION™ Anterior Cervical Plating System is substantially equivalent to the following predicate devices:

Trade/Proprietary Name	Manufacturer	Clearance
CSLP	Synthes Spine	K000536
Stella	Scient'x	K042317

Performance Data:

Mechanical and dynamic testing of the cervical plate system was performed. The test results demonstrate that the mechanical performance of the NEXT GENERATION™ Anterior Cervical Plating System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alphatec Spine, Inc.
% Ms. Paula Morgan
Director of Regulatory Affairs
& Compliance
2051 Palomar Airport Road, Suite 100
Carlsbad, California 92011

MAY - 4 2007

Re: K070681
Trade Name: NEXT GENERATION™ Anterior Cervical Plate System
Regulation Number(s): 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 20, 2007
Received: April 25, 2007

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address: http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: NEXT GENERATION™ Anterior Cervical Plating System

Indications for Use:

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- trauma (i.e., fracture or dislocation)
- spinal stenosis
- pseudoarthrosis
- tumor
- and failed previous fusion.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueno

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070681